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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,768	01/30/2004	Frieder U. Maerz	1/1090-1-C1	7043

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

MAIL DATE	DELIVERY MODE
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05/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,768	Applicant(s) MAERZ, FRIEDER U.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a continuation application of application 09/337789.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 17-28, 30-33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kielley et al. (US 5,114,979, IDS), in view of Geimer (WO 97/18902, US 6,053,368 is the English equivalent).

1. Kielley teaches a nasal spray composition comprises essentially decongestant oxymetazoline HCl, sorbitol, a buffer such as phosphate, and aqueous solvent. The amount of the decongestant employed is known in the art to be 0.01% to 0.1% by weight. The composition also contains fruit flavor for masking the after-taste. See columns 2-3 and the claims. Kielley also reveals that similar composition but without the fruit flavor is known in the art. See, column 1, lines 9-38. The amount of sorbitol is about 2.8 to 4.9% by weight (4 –7% of 70% sorbitol solution), the pH is within the range of 4.0 to 6.5, sodium hydroxide may be used for adjust the

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pH. (column 1, lines 56-68, and the examples). The composition is isotonic, any tonicity agents well known in the art may be used instead of sorbitol. (col. 2, lines 55-62). Kielley also discloses a container (inhaler) containing the nasal spray composition and with means for dispensing the composition to nasal cavity. See, particularly the claims.

2. Kielley does not teach expressly a inhaler containing the isotonic formulation comprising oxymetazoline; sorbitol; water, or mixture of water/ethanol; and an inorganic buffer, wherein the inhaler comprises an oligodynamic active metal, such as silver.

3. However, Geimer teaches an aerosol dispensing apparatus for fluid from a storage vessel. The apparatus is characterized as having a fluid outlet area with a surface having substance which have an oligodynamic effect or germ-reducing properties for sterilizing, degerminating or reducing the germs in fluid, wherein the substance is silver. See, particularly the claims.

4. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to make a inhaler containing the isotonic formulation comprising oxymetazoline; sorbitol; water, or mixture of water/ethanol; and an inorganic buffer, wherein the inhaler comprises an oligodynamic active metal, such as silver. A person of ordinary skill in the art would have been motivated to make a inhaler containing the isotonic formulation comprising oxymetazoline; sorbitol; water, or mixture of water/ethanol; and an inorganic buffer, wherein the inhaler comprises an oligodynamic active metal, such as silver because the inhaler with the oligodynamic active metal will prevent the fluid from contamination by microorganism. Further, the employment of the well-known buffer systems herein is within the purview of skilled artisan to reach the designed pH. Furthermore, the optimization of a result

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effective parameter, e.g., the amounts of tonicity agents, pH etc within the disclosed range, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

4. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kielley et al. (US 5,114,979, IDS), in view of Geimer (WO 97/18902, US 6,053,368 is the English equivalent) for reasons discussed above, and in further view of Guy (US 5,540,930).

5. Kielley et al. and Geimer as whole do not teach expressly the employment of glycerol.

6. However, Guy et al. teaches that glycerol is a well-known tonicity agent used in topical pharmaceutical composition. The amount employed is about 2.0 to 2.8% by weight. See, particularly, col. 4, lines 30-35.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use glycerol as tonicity agent in the composition of Kielley et al. as Kielley disclosed that any suitable tonicity agents may be used and glycerol is a known tonicity agent suitable for topical pharmaceutical composition.

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kielley et al. (US 5,114,979), in view of Geimer (WO 97/18902, US 6,053,368 is the English equivalent) for reasons discussed above, and in further view of Merck Index, 11th Edition, pages 1102.

6. Kielley et al. and Geimer as whole do not teach expressly the employment of ethanol with water as the solvent.

7. However, Merck index reveals that oxymetazoline is known to be soluble in water and ethanol. See, pages 1102, items 6919.

8. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use water/ethanol mixture as the solvent in the

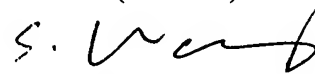
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composition of Kielley et al. because oxymetazoline is soluble in water and ethanol. The employment of water/ethanol mixture is an obvious variation of water since oxymetazoline is known to be soluble in water and ethanol.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shengjun Wang
Primary Examiner
Art Unit 1617